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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,772	06/15/2000	DEREK O'HAGAN	PP01388.202	7681

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EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/27/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/581,772	O'HAGAN ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- Th MAILING DATE of this communication appears on the cov r sh t with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-16,43-47,52-54,56-59 and 69-103* is/are pending in the application.

4a) Of the above claim(s) *9, 52, 53, 81-84, 91-93, 98, 99, and 103* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-16,43-47,54-59,6[illegible]-80,85-90,94-97 and 100-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the ClaimsIn the prior action mailed on April 24, 2002, claims 1-7, 9-19, and 43-47, 52-54, 56-59, and 69-90 were pending in the case, and claims 1-7, 10-16, 43-47, and 54, 56-59, 69-80, and 85-90 were under consideration and rejected. It is noted that claim 9 was erroneously identified as under consideration. As indicated by the Applicant in the Response, the claim is currently withdrawn from consideration as to a non-elected invention.

In the Response filed by applicant on June 16, 2003, claims 1, 9, 43, 70, and 73 were amended; and claims 91-103 were added.

Currently claims 1-7, 9-16, 43-47, 52-54, 56-59, and 69-103 are pending. Claims 1-7, 10-16, 43-47, 54-59, 69- 80, and 85-90 are under consideration. Claims 9, 52, 53, and 81-84, and claims 91-93, 98, 99, and 103 are withdrawn from consideration as reading on non-elected inventions.

2. Because this action raises new issues not raised in a prior action, it is being made Non-Final.

Election/Restrictions

3. Newly submitted claims 91-93, and 103 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: these claims read either on methods of using previously withdrawn products, or on products and methods of using products comprising tumor antigens, where the claims previously under examination were

directed to antigens of pathogenic organisms, although the claims under examination include claims generic to the previously elected, and the newly added claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 91-93, 98, 99, and 103 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

4. Claim 69 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As currently written, the independent claims exclude the incorporation of antigens within the microparticles. Thus, the limitation of claim 69 is not further limiting of the claims from which it depends.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **(Prior Rejection-Withdrawn)** Claim 73 was rejected in the prior action under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention. In view of the amendment to this claim, the rejection is withdrawn.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(New Rejection)** Claims 1-5, 7, 10-16, 44-47, 54, 56-57, 59, 69-80, 85-90, 94-97, and 100-102 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for microparticles with a polynucleotide antigen adsorbed to the surface wherein the detergent is cationically charged, does not reasonably provide enablement for such microparticles wherein the detergent is anionically charged. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The claims read on microparticles comprising a biodegradable polymer, an antigen, and a detergent wherein the detergent is selected from a cationic or anionic detergent, and wherein the antigen is a polynucleotide. The Applicant has provided examples of microparticles with polynucleotide antigens adsorbed thereto wherein the particles comprise a cationic detergent. See e.g., pages 28-29, and 38-39. However, the Applicant has not shown that microparticles comprising anionic detergents would be capable of the successful delivery of polynucleotide antigens.

While the Applicant has demonstrated the use of the microparticles with anionic detergents, each of these examples is shown to adsorb protein antigens, and not polynucleotides.

See, pages 24-28. As indicated in the art, and supported by the examples, due to the negative charges of polynucleotides, these antigens efficiently bind to carriers with positive charges. See, Bertling and Unger as applied in the prior action. However, one skilled in the art would not expect the negatively charges polynucleotides to bind to negatively charged carrier particles on the surface of these particles, or that such carriers could deliver the polynucleotides to cells for uptake and expression. Thus, the Applicant is not enabled for the claimed invention to the extent that the claims read on microparticles with anionic detergents and wherein the antigen adsorbed to the surface is a polynucleotide.

9. **(New Rejection)** Claims 1-7, 10-16, 44-47, 54, 56-59, 69-80, 85-90, 94-97, and 100-102 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the microparticles comprising the polymers identified in claim 1, does not reasonably provide enablement for the claimed microparticles comprising any biodegradable polymer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The claims read on embodiments wherein the claimed microparticles may comprise any biopolymer. In the case of claim 1, any polymer may be used in combination with one of the identified polymers, whereas in claim 43, any biopolymer may be used.

As indicated by the Applicant in response to the rejection of the claims over Levy in view of Bertling, the Bertling reference indicated that nanoparticle comprising DEAE-dextran as the biopolymer was an effective carrier of polynucleotide antigens, but that the nanoparticle was not an effective delivery mechanism of the antigen. This is because the nanoparticle, while it could

carry the DNA to a cell, did not allow for the transcription of the DNA upon arrival at the cell. Thus, from this reference those in the art would have known that not every biopolymer containing microparticle would be capable of effectively delivering polynucleotide antigens to a cell. However, while the Applicant has identified certain varieties of biopolymer containing microparticles that were so effective, the Applicant has not demonstrated that every embodiment of the claimed invention would be capable of effectively delivering polynucleotide antigens to cells. Nor has the Applicant provided any teachings that would indicate what biopolymers would, and would not be capable of effectively delivering such antigens. In view of the above, the Applicant is not enabled for the full scope of the presently claimed invention.

Claim Rejections - 35 USC § 102

10. **(Prior Rejection-Withdrawn)** In the prior action, claims 1, 4, 5, 7, 43, 45, 46, and 78 were rejected under 35 U.S.C. § 102(a) as being anticipated by Levy et al. (WO 96/20698). In view of the Amendment of the claims, and the arguments pursuant thereto, this rejection is withdrawn.

Claim Rejections - 35 USC § 103

11. **(Prior Rejection-Withdrawn)** Claims 1-7, 11, 13, 14, 43-47, 54, 56, 57, 75, 76, and 78 were rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. in view of Unger et al., U.S. Patent 5,830,430 or alternatively in view of Bertling et al., Biotech, and App. Biochem., 13:390-405. In view of the arguments made by Applicant regarding the Bertling reference, demonstrating that the art teaches away from the use of charged nanoparticles (therefore

presumably also microparticles) for the delivery of polynucleotide antigens, the rejection is hereby withdrawn.

Because the further rejections over Levy in view of either Unger or Bertling, and further in view of Eswarakkrishnan and Rembaum; further in view of Moore and Haynes; further in view of Cleland; or further in view of Hedley each depend on the teachings of Levy in view of Unger and Bertling, and because none of these further references meet the deficiencies of the primary rejection; these further rejections are likewise withdrawn.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
August 25, 2003

JAMES HOUSEL 8/25/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600